510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
K042815

B. Purpose for Submission:
New device

C. Measurand:
CA 125, CA 19-9, CA 15-3, CA 27.29

D. Type of Test:
Quality control material for automated testing

E. Applicant:
Bio-Rad Laboratories

F. Proprietary and Established Names:
Quest Diagnostics Tumor Marker Control Levels 1, 2, and 3

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1660, Quality control material (assayed and unassayed)

2. Classification:
   Class I

3. Product code:
   JJY, Multi-analyte controls all kinds (assayed and unassayed)

4. Panel:
   Chemistry 75

H. Intended Use:

1. Intended use(s):
   Quest Diagnostics Tumor Marker Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

2. Indication(s) for use:
   Same as the Intended use(s)

3. Special conditions for use statement(s):
   Prescription use

4. Special instrument requirements:
   Instruments listed in the package insert: Abbott AxSYM (CA 125 and CA 15-3) and the Bayer ADVIA Centaur (CA19-9 and CA 27.29)

I. Device Description:

The Quest Diagnostics Tumor Marker Control is a human serum based product containing constituents of human and animal origin and added chemicals. The controls are provided in lyophilized form at 3 levels.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bio-Rad Laboratories Lyphochek Tumor Marker Control

2. Predicate 510(k) number(s):
   K011579

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Serum	Same
Form	Lyophilized	Same
Storage – unopened	2° - 8°C until expiration date	Same
Stability after reconstitution and freezing	All analytes 30 days at -10° to -20°C	Same
Preservatives	Does not contain preservatives	Same

Differences		
Item	Device	Predicate
Constituents	CA 15-3, CA 125, CA 19-9, CA 27.29	CA 15-3, CA 125, CA 19-9, CA 27.29 plus ACTH*, AFP, aldosterone*, β-2 micro-globulin*, CA 50**, CA 72-4**, calcitonin*,

Differences		
Item	Device	Predicate
		CASA**, CEA, CYFRA 21-1**, ferritin*, hCG*, hCG – beta subunit*, neuron specific enolase**, PAP, prolactin*, PSA
Levels	3 levels	2 levels
Reconstituted vial claims	All 4 analytes 14 days at 2° - 8°C	CA 27.29 stable for 6 days

* Not cleared or approved as tumor markers in the US
** Not cleared or approved in the US

K. Standard/Guidance Document Referenced (if applicable):
None referenced.

L. Test Principle:
Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   Not applicable.

   b. *Linearity/assay reportable range:*
   Not applicable.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
   The controls are not traceable to any recognized reference material. Value assignments were performed according to Bio-Rad's QC material protocol. Mean values presented in the package insert were generated by four Quest Diagnostics Laboratories.

   d. *Detection limit:*
   Not applicable.

   e. *Analytical specificity:*
   Not applicable.

   f. *Assay cut-off:*
   Not applicable.

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Not applicable.

b. Matrix comparison:
Not applicable.

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.

   b. Clinical specificity:
   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   Not applicable.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.